JUN 1 4 2000

K001660

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.

Manufacturer: Biomet Manufacturing, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Proprietary Name: Mallory Head Modular Calcar

Common or Usual Name: Modular metallic total hip system

Classification Name: Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented (888.3358)

Device Classification: Class II

Device Product Code: 87LPH

Device Description: The predicate to the Mallory Head Modular Calcar – the Mallory Head Modular Calcar- was previously cleared in K945115. The distal portion of the predicate has been modified by removing the distal slot and making the stem 100% porous coating. The modified and predicate devices are made of the same material (Ti-6Al-4V conforming to ASTM F-136) and intended for non-cemented use. For a complete characterization of Biomet's plasma spray porous coating see Masterfile MAF-153.

The modified device may be used with any Biomet modular proximal component (a complete listing of proximal components can be found in Exhibit II). As with the predicate, the proximal body and the distal stem are joined by means of a Morse locking taper. The trunion of the distal stem has a two (2) degree included angle which mates with a matching bore on the proximal segment. Additional fixation is achieved through a locking screw inserted through the driving platform and engaging with the stem taper.

Indications For Use: 1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) rheumatoid arthritis; 3) correction of functional deformity; 4) revision procedures where other treatment or devices have failed; 5) treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 4 2000

Ms. Michelle L. McKinley
Regulatory Specialist
Biomet Inc.
P.O. Box 587
Warsaw, Indiana 46581

Re: K001660
Trade Name: Mallory Head Modular Calcar
Regulatory Class: II
Product Code: LPH
Dated: April 20, 2000
Received: May 31, 2000

Dear Ms. McKinley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bochner.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001660

Device Name: Mallory Head Modular Calcar

Indications for Use: 1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) rheumatoid arthritis; 3) correction of functional deformity; 4) revision procedures where other treatment or devices have failed; 5) treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE OF ANOTHER PAGE IF NEEDED)

Donna R. Vochmes

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001660